K003910 MAR 1 9 2001

510(k) Summary of Safety and Effectiveness
***NexGen*® Complete Knee Solution Crosslinked Polyethylene**
Cruciate Retaining (CR) articular surface components

I. Submitted by:

Zimmer, Inc.
P.O. Box 708
Warsaw, Indiana 46581-0708

II. Contact Person:

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Regulatory Affairs
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III. Date Prepared:

March 9, 2001

IV. Name of Device:

A.	Trade Name:	Articular Surface Knee Component
B.	Proprietary Name:	*NexGen*® Complete Knee Solution, Crosslinked Polyethylene Cruciate Retaining (CR) articular surface component
C.	Common Name:	Crosslinked Polyethylene CR Articular Surface
D.	Classification Name and Reference:	Knee joint patellofemorotibial polyethylene/metal/ polyethylene semiconstrained cemented total knee prosthesis – 21 CFR 888.3560

E. Predicate Device:

NexGen® Complete Knee Solution CR Knee

F. Device Description:

This device is an integral component of the *NexGen* cruciate retaining (CR) knee; a semiconstrained, nonlinked condylar system designed for use with a functional posterior cruciate ligament. Like the predicate, this device can also be used when both cruciates

are excised with some potential loss in kinematic function. It is available in a variety of thicknesses to facilitate ligament balancing and joint line restoration.

The proposed device is identical to the predicate device except that it is manufactured from Ultra-High Molecular-Weight Polyethylene (UHMWPE) that has been crosslinked by electron-beam (e-beam) radiation to provide additional wear resistance and then sterilized using gas plasma.

G. Intended Use:

This device is intended to reduce or relieve pain and restore function and motion to the knee joint. Total knee replacement is indicated for patients with severe knee pain and disability due to rheumatoid arthritis, osteoarthritis, primary and secondary traumatic arthritis, polyarthritis, collagen disorders, avascular necrosis of the femoral condyle or pseudogout, posttraumatic loss of joint configuration, particularly when there is patellofemoral erosion, dysfunction or prior patellectomy, moderate valgus, varus, or flexion deformities. This device may also be indicated in the salvage of previously failed surgical attempts if the knee can be satisfactorily balanced and stabilized at the time of surgery.

The Zimmer *NexGen* polyethylene cruciate retaining articular surfaces (size Green C-H; 9 mm thick; e-beam crosslinked at 65 kGy and gas plasma sterilized), had a wear reduction of 81% over the Zimmer *NexGen* control articular surfaces (gamma sterilized at 37 kGy). The amount of wear for each was 2.72 mg/million cycles and 14.4 mg/million cycles, respectively. Testing was performed in undiluted bovine calf serum using an AMTI multiaxis knee joint simulator for 5 million cycles. Load was applied using a cobalt-chromium-molybdenum femoral component with a maximum load of 3200 N. These crosslinked components are designed for posterior cruciate ligament retention. The results of *in vitro* wear tests have not been shown to correlate with clinical wear mechanisms.

The *NexGen* crosslinked polyethylene cruciate retaining articular surfaces are intended to be used as part of a cemented knee system.

H. Comparison to Predicate Device:

Parameter	Identical, Similar or Different?	Similarities and Differences
Design	Identical	• All dimensions are identical for the predicate and proposed articular surfaces. • Compatibility between femoral and tibial baseplate components are identical for the predicate and proposed articular surfaces.
Materials	Identical	• Material is UHMWPE for both the predicate and the proposed articular surface.
Manufacturing process	Similar	• The manufacturing process is identical except for the addition of crosslinking and melt annealing steps to the proposed articular surfaces.

Biocompatibility	Identical	• Biocompatibility testing (short term toxicity) was conducted per AAMI/ANSI/ISO 10993-1 and GLPs and is on file at Zimmer. The materials used meet or exceed ASTM standards, are common to orthopedic products today, and have an extensive safe clinical history.
Pyrogenicity	Identical	• Neither the predicate or the proposed articular surfaces are labeled as nonpyrogenic. Per USP XXIII, NF18 (1995 edition), page 1719, "These requirements do not apply to orthopaedic products."
Sterility	Different	• The predicate device is terminally sterilized by gamma radiation. Gamma radiation processing and dose mapping are conducted according to ANSI/AAMI/ISO 11137-1994. The products are accepted for release as sterile though a validated dosimetric release program designed to provide a sterility assurance level (SAL) of 10^{-6} or better (ANSI/AAMI/ISO 11137-1994, ANSI/AAMI ST32-1991 and ISO/TR 13409-1996). • The proposed device is terminally sterilized by the STERRAD 100 Hydrogen Peroxide Gas Plasma system (Advanced Sterilization Products). The sterilization process was validated using the half-cycle microbial challenge overkill method. This overkill method, which has been traditionally used to validate industrial steam and ethylene oxide sterilization processes, was applied to the gas plasma sterilization process to demonstrate a sterility assurance level of 10^{-6} or better.

I. Non-clinical Performance and Conclusions:

1. The tibial baseplate interlock mechanism for the device is the same as the predicate device. However, because the material characteristics changed, the interlock mechanism was tested and passed.

2. No additional fatigue strength or lateral stability of the patellofemoral joint data was needed because the device uses the predicate tibial baseplate and/or femoral components.

3. No additional shear strength or metal-backed patella static tensile data was needed because the device uses the predicate patella components.

4. Both a standard wear and wear in the presence of bone cement particles showed significant wear reduction for the proposed device over the predicate.

5. There was no significant difference between the proposed device and the predicate in delamination characteristics. Both passed.

J. Clinical Performance and Conclusions:

Clinical data and conclusions were not needed for this device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 1 9 2001

Mr. Stephen McKelvey
Senior Regulatory Affairs Associate
Zimmer, Inc.
P.O. Box 708
Warsaw, Indiana 46581-0708

Re: K003910
Trade Name: NexGen® Complete Knee Solution, Crosslinked Polyethylene Cruciate Retaining (CR) Articular Surface Components
Regulatory Class: II
Product Code: JWH
Regulation: 21 CFR 888.3560
Dated: December 18, 2000
Received: December 19, 2000

Dear Mr. McKelvey:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

for Mark N Melkerson

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative and
Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K003910

Device Name:

NexGen® Complete Knee Solution, Crosslinked Polyethylene Cruciate Retaining (CR) articular surface components

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Concurrence of CDRH, Office of Device Evaluation (ODE)

for Mark N. Melkerson

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K003910

Prescription Use X
(Per 21 CFR 801.109)

OR

Over-The-Counter Use ____
(Optional Format 1-2-96)